EXPORT OF BLOOD AND BLOOD PRODUCTS OF ANIMAL ORIGIN INTENTED FOR PHARMACEUTICAL OR TECHNICAL USE TO IRELAND

Requirements valid only until the implementation of REGULATION (EC) 1774/2002.

Import requirements provided by the Department of Agriculture and Food, Dublin.

The following conditions apply to the importation of blood and blood products of ungulates and poultry (with the exception of serum from equidae) intended for pharmaceutical or technical use and not intended for human or animal consumption:

"Blood" means whole blood defined as low-risk material within the meaning of Directive 90/667/EEC.

"Blood products" means

a) fractions of blood which may have undergone treatment other than that provided for in Directive 90/667/EEC, or
b) blood which has undergone treatment other than that provided for in Directive 90/667/EEC.

"Full treatment" means any one of the following treatments:

(a) heat treatment at a temperature of 65 degrees for at least 3 hours;
(b) heat treatment to a minimum Fc of 3.0 (as provided for in Chapter 4 of the Annex to Council Directive 92/118/EEC;
(c) irradiation at 2.5 megarads, by gamma rays, followed by an effectiveness check;
(d) change in pH to pH5 for 2 hours followed by an effectiveness check;
(e) any other treatment or process laid down and approved by the EU Commission.

1. The exporter should be advised to have their Irish importer obtain an import permit prior to the product arriving in Ireland by contacting:

John Flannery
Product Import Section
Animal Health and Welfare Division
Department of Agriculture and Food
Kildare Street
Dublin 2
Telephone: 011-353-1-707-2000 ext.3684
Fax : 011-353-1-662-9237

2. The product must come from an establishment which has been approved by

the EU Commission or failing that by the competent authority of the exporting country, and have an approval number.

3. Each consignment must be accompanied to the border inspection post by an animal health certificate signed by an official veterinarian of the exporting country and certifying that the products:

(a) originate in a third country in which no case of foot-and-mouth disease has been recorded within at least 24 months and no case of vesicular stomatitis, swine vesicular disease, rinderpest, peste des petits ruminants, Rift Valley fever, **blue tongue**, African horse sickness, classical swine fever, African swine fever, **Newcastle disease** or **avian influenza** has been recorded for 12 months in the susceptible species and in which vaccination has not been carried out against those diseases for at least 12 months. The health certificate may be made out according to the species of animal from which the blood products are derived,

OR

(b) in the case of blood products derived from bovine animals originate in an area of a third country fulfilling the conditions set out in sub-paragraph (a) above from which imports of bovine animals, their fresh meat or their sperm are authorized pursuant to Community legislation. The blood from which such products are manufactured must be from bovine animals from that area of the third country and must have been collected:

(i) in slaughterhouses approved in accordance with Community legislation.

or

(ii) in slaughterhouses approved and supervised by the competent authorities of the third country.

OR

(c) in the case of blood products derived from bovine animals, have undergone full treatments guaranteeing the absence of pathogens of the bovine diseases referred to in sub-paragraph (a) above,

OR

(d) **in the case of blood products derived from bovine animals, fulfill the conditions laid down in Chapter 10 of Annex 1 to Directive 92/118/EEC.** In such cases, the packaging may not be opened during storage and the processing undertaking must carry out full treatment of the products concerned.

4. In the case of blood products, which are not accompanied by assurances with regard to the absence of the blue-tongue virus, the products must be tested in the country of origin for the absence of the blue tongue virus in a laboratory approved and supervised by the competent authority. The certified negative test results must be attached to the animal health certificate.

5. The blood products must be enclosed in watertight and properly sealed containers and must be consigned directly to the processing establishment. The containers and the accompanying documents must be marked; "BLOOD PRODUCTS OF ANIMAL ORIGIN FOR TECHNICAL OR PHARMACEUTICAL USE", depending on the intended purpose. The containers and the accompanying documents shall also bear the name and address of the consignee.

6. Veterinary certificate must also include the Supplementary SRM statements (located on the Ireland Iregs).

CHAPTER 10 OF ANNEX I TO DIRECTIVE 92/118/EEC

(for bovine products that have not been "fully treated")

Raw material for the manufacture of animal feedingstuffs and pharmaceutical or technical products

1. Raw material means fresh meat, glands, organs and other offal as well as intestinal mucuses which are not intended for human consumption. Raw material shall be regarded as fresh if it has only undergone refrigeration or other treatment not resulting in sufficiently safe destruction of pathogenic agents. The substance involved may only be low-risk substances within the meaning of Directive 90/667/EEC.

2. Raw material must be accompanied by a commercial document or certificate, provided for in article 13 (2) of Directive 90/667/EEC, or a certificate complying with the model to be laid down under the procedures provided for in Article 18 and must satisfy the requirements of Decision 92/183/EEC.

3. In trade the original of the health certificate or commercial document must be submitted to the veterinary authorities responsible for the processing plant and the intermediate storage warehouse – cold storage facility – or sorting facility; in the

case of imports into the community, it must be submitted to the border control authority.

4. The raw material must be transported directly to approved or registered processing plants which meet the conditions laid down in Directive 90/667/EEC or to cold-storage facilities approved for intermediate storage. Prior to processing, raw material for manufacturing pharmaceuticals may also be sorted and stored in facilities specially approved for the purposed by the Member States. Member States shall inform the Commission of the approval of such sorting facilities.

5. The raw material may be transported to the processing plant only in watertight and properly sealed containers or vehicles. The legend 'Only for the manufacture of petfood' or 'Only for the manufacture of pharmaceuticals or technical products' must appear on the recipients and accompanying documents, depending on the intended purpose. The name and address of the consignee undertaking must appear on the containers and accompanying papers.

6. The vehicles and containers used to transport the goods, together with all items of equipment or appliance which have come into contact with the untreated raw material, must be cleaned and disinfected. Packaging material must be incinerated or disposed of by some other means in accordance with instructions from the official veterinarian.

7. Intermediate storage of the raw material shall be permissible only in cold storage facilities approved for the purpose, subject to authorization and under the supervision of the official veterinarian. The raw material must be stored separately from other goods and in such a way as to prevent any propagation of epizootic disease.

8. At the processing plant the raw material shall be treated in such a way as to kill any pathogenic agents and rule out any danger to domestic herds. Removal of raw material from the plant for safe disposal in processing plants approved or registered for the purpose in accordance with Directive 90/667/EEC shall be permissible only in exceptional cases and with the authorization of the official veterinarian. The provision of points 5, 6 and 9 shall apply correspondingly to the transportation of the raw material and to the notification of the official veterinarian responsible for the processing plant.

9. When the raw material transported from the plant of origin, or beyond the Community's external border:

    - the official veterinarian responsible for the plant of origin in the case of intra - Community trade, or

    - the border inspection authority in the case of imports into

the Community Shall notify the official veterinarian responsible for the processing plant, Intermediate storage warehouse or sorting facility of the fact by means of the 'Animo system', by telex or by fax.

10. Imports into the Community are also subject to the following provisions:

(a) Member states shall authorize the importation of raw Material into the Community only from third countries which appear on the list down in Council Decision 79/542/EEC or in a special Commission Decision on a specific raw material;

(b) Following the border check the raw materials shall, under the supervision of the competent veterinary authority, be transported either directly to an approved or registered processing plant which is under the constant supervision of an official veterinarian and has given a guarantee that the raw materials will be used only for the permitted purpose and that they will not leave the plant untreated, or to an approved intermediate storage or approved sorting facility;

(c) The health certificate bearing the file mark of the border inspection authority or a certified copy of that certificate must accompany the goods until they reach the destination plant.